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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/608,701 | 06/27/2003 | Mark V. Vandewalle | 5490-000283 | 9681 |
| 27572 | 7590 | 09/19/2006 | | |
| HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303 | | | | |
| | | | EXAMINER | |
| | | | ARAJ, MICHAEL J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,701

Applicant(s)

VANDEWALLE, MARK V.

Examiner

Michael J. Araj

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13-15,17-30 and 32-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-11,13-15,17,18 and 42 is/are allowed.
- 6) ☒ Claim(s) 34-41 is/are rejected.
- 7) ☒ Claim(s) 19-30,32,33,43 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1,3-11,13-15,17-30 and 32-44 are pending.

Claim Objections

Claims 19-33 and 43-44 are objected to because of the following informalities:

These claims introduce the term "a neck portion" that is not disclosed in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant introduces "a bone cement region" which does not appear to have support described in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultheiss et al. (U.S. Patent No. 6,755,835) in view of Wolf (U.S. Patent No. 6,629,977).

Schultheiss et al. discloses a bone screw anchor (10) that is operable to secure an implant to a bone that has and externally threaded (14) intermediary portion; a pointed self-tapping tip, comprising of a cutting flute that extends across a part of the intermediary portion, located at a first end of said intermediary portion; a collared head, comprising of a cutting flute, located at a second end opposite of said tip that has an interface capable with a driving tool; and a threaded interior (55) bore (50) extending through said head and through said intermediary portion, where it is operable with threads of the fastening device (a screw) to secure the implant to the bone (see Fig. 1 below). Schultheiss et al. also discloses a port (62) on the sides of the anchor that can communicate with the interior bore (50) that is at least partially filled with bone cement, an intermediary portion that is completely threaded that has a larger diameter than the tip and an interface of said head that has at least one recess (54) operable to mate with said driver.

Schultheiss et al. discloses the method steps of securing an implant to a bone which includes implanting a bone screw anchor within the bone using a driving tool operable with the head of the anchor; injecting bone cement into a threaded bore extending through the head to at least a portion of the intermediary portion using a cement delivery device that allows the anchor to be secured; and securing the implant to the anchor using a threaded fastening device secure within the bore. Schultheiss et al. also discloses that the internally threaded portion is inherently protected during the ejecting step, the delivery device is connected to the internal thread of the anchor to protect the threads from being contaminated with bone cement during the injecting step and the bone cement exits at least one port located on the side of the anchor.

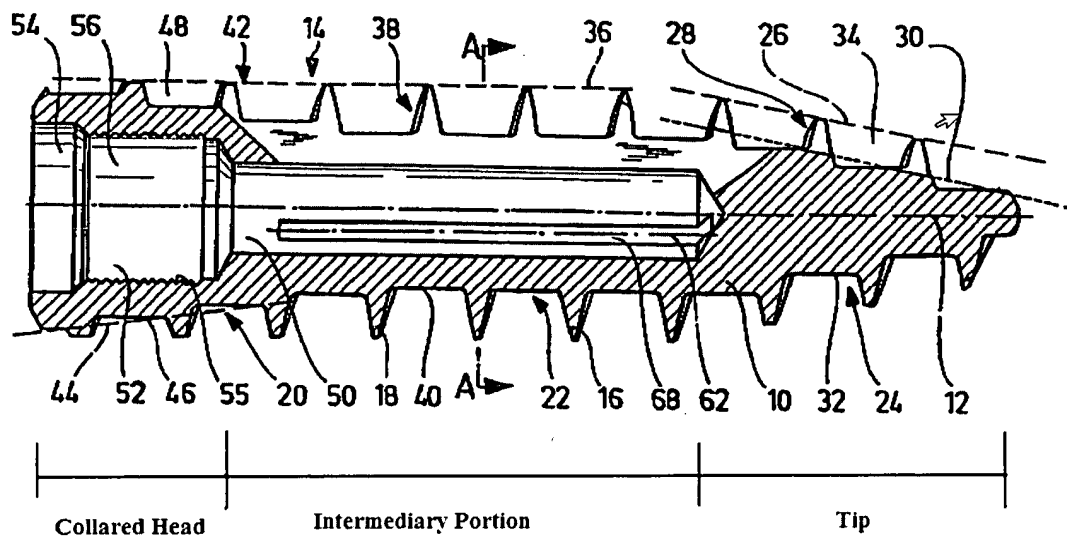


Figure 1

Schultheiss discloses the claimed invention except for and open tip or a screw head having grooves. Wolf discloses a groove to receive a driving tool to optimize

Art Unit: 3733

torque capacity when inserting the device. Wolf also discloses an open tip (30) so that a guide pin may be used during delivery and installation. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Schultheiss with a head defining a groove as well as an open tip in view of wolf, in order to have a device that can be installed with ease and accuracy.

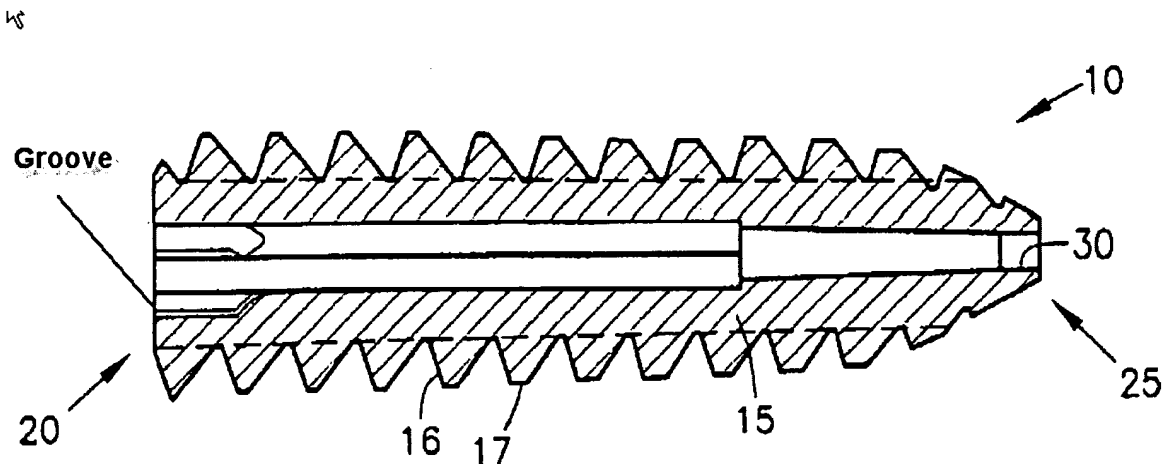


Figure 2

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultheiss et al. (U.S. Patent No. 6,755,835) in view of Baker et al. (U.S. Patent No. 5,569,251).

Schultheiss et al. disclose the claimed invention including threading a fastening device into the anchor to a depth not beyond a tip (24) of the anchor except for placing an implant over the anchor and fastening the implant to the anchor using a fastening device. Barker et al. disclose the method of placing the implant, in this case a bone plate, over the anchors and using a fastening device to the anchor in order to secure the assembly and strengthen the bone. It would have been obvious to one skilled in the art

at the time the invention was made to have the method of securement of schultheiss and applying it with a bone plate in view of baker et al., in order to have secure support for a damaged bone and allow it to heal accordingly.

Response to Arguments

Applicant's arguments with respect claims 34-38 is moot due to the claimed subject matter being considered as new matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

Art Unit: 3733

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MJA


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER